

### **REMARKS**

This Amendment is in response to the Office Action mailed February 22, 2006, having a three (3) month shortened statutory period for reply. A Petition for a One (1) Month Extension of Time in accordance with 37 C.F.R. §§ 1.136(a) and 1.17(a) is submitted herewith.

Claims 1-11, 13, 15-25 and 34 are pending, claims 1-6, 15 and 18 are rejected and claims 16 and 17 are objected to in this application. Claims 12, 14 and 26-33 are cancelled.

Claims 1-5 and 16-17 are amended for the sake of clarification or to correct inadvertent typographical errors made therein. All claim amendments are reflected in the Listing of Claims section (see, pages 2-33).

No new matter has been added to the claims or specification by the amendment. Support for all amendments are found in the originally filed claims and specification.

Applicants request consideration and entry into the record of the following amendments and remarks.

### **Restriction Requirement**

In summary of the preceding prosecution history, applicants elected with traverse for prosecution on the merits in response to the July 28, 2005 Restriction/Election Requirement:

Group I: claims 1-12, 13 and 15-18, drawn to a compound of formula I; and the species of Example 59:

4-[[N<sup>α</sup>-(4-pyridinylmethoxycarbonyl)-L-leuciny]amino]-1-(2-pyridylsulphonyl)-3-pyrrolidinone,

which has been acknowledged by the Examiner in the February 22, 2006 Office Action.

In the subsequent February 22, 2006 Office Action the Examiner states that:

“claims 1-11, 13, 15-25 and 34 are pending” . . . Group I was indicated with further restriction and this broken down as follows:

Group Ia: claims 1-6 and 15-18, drawn to compounds of formula I wherein n=0; A is C(O); R<sup>1</sup> is R<sup>4</sup>-N(R<sup>6</sup>)-CH(R<sup>3</sup>)-Z-; R<sup>2</sup> is R<sup>5</sup>SO<sub>2</sub>-; R<sup>5</sup> is pyridinyl or pyridyl; Pharmaceutical composition thereof . .

Group Ib: claims 1, 7-11, 13 and 15-18, drawn to compounds of formula I with the remaining substituents, pharmaceutical composition thereof . . . ,

“the elected species falls within Group Ia and thus only claims 1-6 and 15-18 are considered . . . [and that] non-elected claims 7-11, 13, 19-25 and 34 are withdrawn from consideration as being drawn to non-elected subject matter.”; and that

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applicants “traversal is not found persuasive because a common utility is not sufficient to keep all distinct species in the same invention. In the instant case, formula I does not really have a common special technical feature . . . Although method of use and process are arisen from the same research, they have different patentability criteria, and must be considered separately from the compounds. Thus, they require additional search , which imposes a serious burden of searching and examining.”

In response to the Examiner’s comments and February 22, 2006 further restriction of Group I, applicants respectfully maintain the traversal of record (see the September 28, 2005 Response to Restriction Requirement).

Applicants also respectfully point out that in accordance with the MPEP Section 821.01, the Examiner may not withdraw claims drawn to a non-elected invention unless a restriction/election requirement is made final.

In the above-identified application, the further restriction of Group I was not made Final by the Examiner in the February 22, 2006 Office Action, such that claims 7-11, 13, 19-25 and 35 cannot be withdrawn from consideration as directed to the non-elected subject matter. Applicants note that the aforementioned claims are not identified as withdrawn in the claim listing section of the present response.

As elected subject matter for examination on the merits is directed to a product, applicants also reserve the right to request rejoinder of commensurate in scope non-elected subject matter or inventions (i.e., such as methods or processes) upon the determination of allowable subject matter (*In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996); also see MPEP § 821.04 (b)).

Moreover, M.P.E.P. Section 809 discusses linking claims where:

“an application has claims to two or more properly divisible inventions, so that a requirement to restrict the claims of the application to one would be proper, but presented in the same case are one or more claims (generally called "linking" claims) inseparable therefrom and thus linking together the otherwise divisible inventions.

Linking claims and the inventions they link together are usually either all directed to products or all directed to processes (i.e., a product claim linking properly divisible product inventions, or a process claim linking properly divisible process inventions). The most common types of linking claims which, if allowable, act to prevent restriction between inventions that can otherwise be shown to be divisible, are

- (A) genus claims linking species claims; and
- (B) subcombination claims linking plural combinations.”

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Upon the indication of allowability of linking claim(s), M.P.E.P. Section 809.03 states that:

“restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with **37 CFR 1.104**. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier (See M.P.E.P. Form Paragraph 8.12). Where the requirement for restriction in an application is predicated upon the nonallowability of generic or other type of linking claims, applicant is entitled to retain in the application claims to the nonelected invention or inventions. Where such withdrawn claims have been canceled by applicant pursuant to the restriction requirement, upon the allowance of the linking claim(s), the examiner must notify applicant that any canceled, nonelected claim(s) which depends from or requires all the limitations of the allowable linking claim may be reinstated by submitting the claim(s) in an amendment. Upon entry of the amendment, the amended claim(s) will be fully examined for patentability (i.e., See MPEP § 821.04 for additional information regarding rejoinder.)”

Applicants further reserve the right to file non-elected inventions as the subject of future applications, which may derive priority from the present application without prejudice.

In light of the above, applicants respectfully request that the Examiner withdraw the above-identified restriction requirement.

#### **Claim Objections and Allowable Subject Matter**

Claims 16 and 17 are objected to for being dependent upon a rejected base claim and indicated to be allowable if amended. The Examiner has stated that those claims encompass specific species and composition not taught or suggested by the art of record or from a search of the relevant art area.

Applicants have overcome the rejection and amended the claims 16 and 17 to be independent claims, which no longer dependent on rejected base claim 1.

In light of this, applicants believe that the claims now are in condition for allowance and respectfully request that the above-identified objections be withdrawn.

#### **Rejection Under 35 U.S.C. §112, 2<sup>nd</sup> paragraph**

Claims 1-6, 15 and 18 are rejected under 35 U.S.C. §112, 2<sup>nd</sup> para., for being indefinite and for failing to particularly point out and distinctly claim the invention.

The Examiner states that in claim 1 a broad recitation of the limitation of the term “Het” is followed by a narrow limitation of specific rings, such that it is unclear what the scope of the terms “R’ ”, “Ar” and “Het” are in relation to each other. The Examiner also

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states that claim 5 lacks antecedent basis as recites terms from claim 1, which are not recited therein.

In the interest of advancing prosecution, applicants have amended claim 1 to obviate the above-identified rejections and for the sake of clarification to correct for minor informalities, such as inadvertent typographical and punctuation errors (i.e., such amendments are reflected in the marked-up claim listings).

Applicants have amended claim 1 to obviate the above-identified rejections. In particular, the recitation of specific heterocyclic rings in claim 1 have been deleted. For the sake of clarification, amended claim 1 now clearly defines specific functional group substituents that contain the sub-substituent "R" as follows:

**"each R' defined above for R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, R<sup>6</sup>, and R<sup>7</sup> and herein below independently is H, C<sub>1-6</sub>alkyl, Ar-C<sub>0-6</sub>alkyl, or Het-C<sub>0-6</sub>alkyl; or phenyl or naphthyl substituted by one to three moieties selected from C<sub>1-4</sub>alkyl, OR', N(R')<sub>2</sub>, SR', CF<sub>3</sub>, NO<sub>2</sub>, CN, CO<sub>2</sub>R', CON(R'), F, Cl, Br and I, or substituted by a methylenedioxy group;**"; and

**"wherein each Ar defined above is independently unsubstituted phenyl or naphthyl; or phenyl or naphthyl substituted by one or more of Ph-C<sub>0-6</sub>alkyl, Het-C<sub>0-6</sub>alkyl, C<sub>1-6</sub>alkoxy, Ph-C<sub>0-6</sub>alkoxy, Het-C<sub>0-6</sub>alkoxy, OH, (CH<sub>2</sub>)<sub>1-6</sub>NR'R', O(CH<sub>2</sub>)<sub>1-6</sub>NR'R'; wherein each R' as defined in Ar independently is as defined for R' above"**

Claim 1 also has been amended to support antecedent basis for the specific functional group substituents as defined in claim 5, which are optionally substituents as attached to the functional groups "phenyl" and "benzyl" (support for this amendment is found at page 5, lines 25-35 to page 6, lines 1-9 of the specification). For the record, the terms "phenyl" and "benzyl" derive antecedent basis from the term Ar-C<sub>0-6</sub>alkyl as defined in claim 1 (i.e., when C=0, the term Ar-C<sub>0-6</sub>alkyl is Ar and when C=1, the term Ar-C<sub>0-6</sub>alkyl is CH<sub>2</sub>Ar or benzyl").

Applicants respectfully notes that the Examiner has not provided any explanation or basis for rejection as to why claims 15 and 18 are indefinite. Clarification is requested so that applicants can address any outstanding issues, if any.

In each of the above-identified amendments, no new matter has been added to the claims of the present application.

In light of the above, applicants request that the above rejection under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, be withdrawn.

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**CONCLUSION**

In view of the above amendments and remarks, applicants believe that the claims of the present application are in condition for allowance and is earnestly solicited.

If any additional fees or charges are required authorization is hereby granted to charge any necessary fees to Deposit Account No. 19-2570 accordingly.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number below.

Respectfully submitted,



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